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Gary M. Nath
NATH & ASSOCIATES PLLC
6th Floor
1030 15th Street
Washington, DC 20005

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,092

Applicant(s)

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 14,15,19-28 and 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,16,17,29 and 30 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges declaration and fee filed 01/03/02/ preliminary amendment filed 10/19/01, IDS filed 01/24/02, extension of time and response to election/restriction requirement filed 03/28/03.

Election/Restrictions

Applicants provisionally elected Group I with traverse. Applicants further elected psychotropic agent and identified claims 1-13 and 16-18 as the claims that read on the elected species. The traversal is on the grounds that there is no serious burden on the examiner to search a controlled or extended release encapsulated product in a caplet form that contains all the active agents recited in instant claim 12. The argument is not persuasive because a caplet comprising hypnotics or hypoglycemic spasmodic is capable of supporting a different patent than a caplet that contains psychotropic agent. A pulsatile release encapsulated product differs from an extended or controlled release encapsulated product and are both capable of supporting different patents within the art. There is a burden to search for all caplet compositions that contain psychotropic agent, insomnia therapeutic agent, ulcer therapeutic agent, anti-emetic agent, anti-diarrheal agent, migraine therapeutic agent or anti-hypertensive agents.

In light of the above discussion restriction and election for examination purposes as indicated in paper number 6 and above is proper. The requirement is still deemed proper and is therefore made FINAL and claims 29 and 30 are included in the examined claims. Thus claims 1-13, 16-18, 29 and 30 are examined.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13, 16, 17, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krishnamurthy (US 5,508,043).

Krishnamurthy discloses a controlled release matrix that comprises active agents (abstract, column 3, lines 3-5) such as anti-histamines, analgesics, anti-inflammatory agents, gastro-intestinals and anti-emetics, anti-epileptics, vasodilators, anti-tussive agents and expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, bronchodilators, anti-inflammatory steroids, antibiotics, psychotropics, anti-diarrheals, mucolytics, sedatives, decongestants, laxatives, antacids, vitamins, stimulants and appetite suppressants (column 7, lines 34-56). The controlled release matrix comprises pharmaceutically acceptable sodium alginate (abstract and column 3) and for tablets and caplets, the matrix also contains generally accepted pharmaceutical lubricants and waxes or fats, magnesium stearate and calcium phosphate (column 6, lines 16-37 and 59-63 and examples 9-11).

Krishnamurthy discloses the caplet composition of the instant claims except that Krishnamurthy is silent on the dimension of the capsule. However, caplets by their nature and design have dimensions of length and diameter and it is within the purview of one of ordinary skill in the art to be able to measure the length and diameter of the caplet. However, it appears

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to the examiner that the dimensions of the caplet does nothing additional to the caplet dosage form since there is no comparable example to demonstrate that the diameter or length of the caplet provides unusual results. Regarding instant claims 4 and 5, one can substitute one erodible polymer with another with the expectation that the polymer will have controlled release properties. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the caplet dosage form of Krishnamurthy where the dosage form comprises active agent, lubricant and sodium alginate. One having ordinary skill in the art would have been motivated to measure the diameter and length of the caplet in order to determine the dimensions of the caplet.

3. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. While Krishnamurthy discloses psychotropic agent, Krishnamurthy does not specifically teach Fluoxetine-HCl psychotropic agent.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84. Copy of Notice of Draftsperson's Patent Drawing Review, Form PTO 948 is attached herewith.

5. Observation:

Cellulose acetate and ethyl acetate are duplicated in claim 5; and line 3, page 39, claim 5, spells cellulose as "cellulose."

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6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
July 23, 2003

